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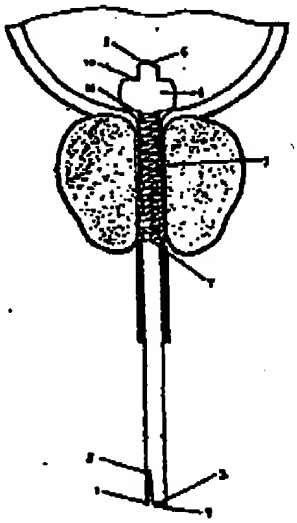
(54)实用新型名称 治疗前列腺增生症记忆合金支架定位导管

(57)摘要

一种治疗前列腺增生症用的记忆合金支架定位导管，它属于医疗器械，它是在已有的尿道普通导管中增加一可充气可排气的气囊，该气囊随定位导管而引入膀胱，注气或液体使气囊膨胀其远端紧抵于膀胱出口处而达到准确定位，使植放在导管侧壁孔处的记忆合金支架在恢复记忆后置于准确的位置，从而达到扩张前列腺部尿道和(或)引流尿液的目的。



(BJ)第1452号

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权 利 要 求 书

1、一种治疗前列腺增生症用的支架定位导管，其特征在于：在导管的近端有一气囊，气囊的远端在膨胀状态下与膀胱出口紧抵。

2、根据权利要求1所述的导管，其特征在于：它是由塑料制成。

3、根据权利要求1所述的导管，其特征在于：它的远端有两个孔，其一是气囊注气孔，其二是尿液引流孔。

4、根据权利要求1所述的导管，其特征在于：在气囊远端下方导管上有均匀分布的侧壁孔。

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说　　明　　书

治疗前列腺增生症记忆合金支架定位导管

本实用新型属于医疗器械，尤其与治疗前列腺增生症置入记忆合金支架有关。

前列腺增生症是老年人常见病多发病之一，由于膀胱出口梗阻，临床上常出现尿潴留、排尿困难等症状，目前新的治疗方法是置入记忆合金支架。但是，现有支架导管不能准确定位，整个操作必须在X光监视下进行，尽管这样，仍有部分病人定位不准确，需反复调整支架位置。

本实用新型的目的是提供一种治疗前列腺增生症用的记忆合金支架定位导管，在没有X光监视下能够准确地将记忆合金支架置入，本支架导管能起到准确定位作用。

本实用新型的目的是这样实现的：定位导管为塑料材料制成，全长25cm，27cm，29cm（不含方叉以后的长度），导管的远端有两个孔，其一是气囊注气孔，其二是尿引流孔，此孔与导管近端开口及记忆合金缠绕处的侧壁孔相通，侧壁孔为两列，侧壁孔均匀排列所占长度为5、6、7cm三种规格，气囊距近端1－2cm，为不变形塑膜，大小为3×3cm，承受压力为2kg／cm²以上，注气后，能起到定位作用，排气后，塑膜紧贴于导管，不增加导管外径，可顺利通过支架内腔拔出支架定位导管，气囊导管的上端（近端）为圆形，有一开口，它与远端尿液引流孔相通。

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由于采用上述方案，可以准确地将支架置入。

下面结合附图和实施例对实用新型进一步说明，

图1 导管正面图

图2 导管横断面图

图3 导管置入图

图中1、气囊注气孔 2、导管尿液引流孔 3、导管侧壁孔 4、导管气囊 5、导管近端 6、近端开口 7、支架 8、方叉 9、导管远端 10、气囊近端 11、气囊远端

采用1%地卡因2ml行尿道粘膜麻醉后，用尿道探子先行尿道扩张，此时利用钛镍合金在低温下柔软容易变形的特性，在约0－10℃盐水中将支架7缠于定位导管侧壁孔处。尿道达到麻醉作用后，将鞘状管先插入尿道，见尿液引出后说明已达膀胱，将带有缠好记忆合金支架的定位导管通过鞘状管导入膀胱，拔出鞘状管，通过气囊注气孔注入气或液体15－30ml，使气囊膨大，轻轻牵拉定位导管远端，使气囊远端抵于尿道内口。通过尿引流孔注入40－50℃温水，温水通过导管侧壁孔与支架接触，支架恢复原形状而起到扩张尿道或（和）引流尿液，放出气囊内气或液体，将定位导管拔出，操作完毕。

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说 明 书 附 图

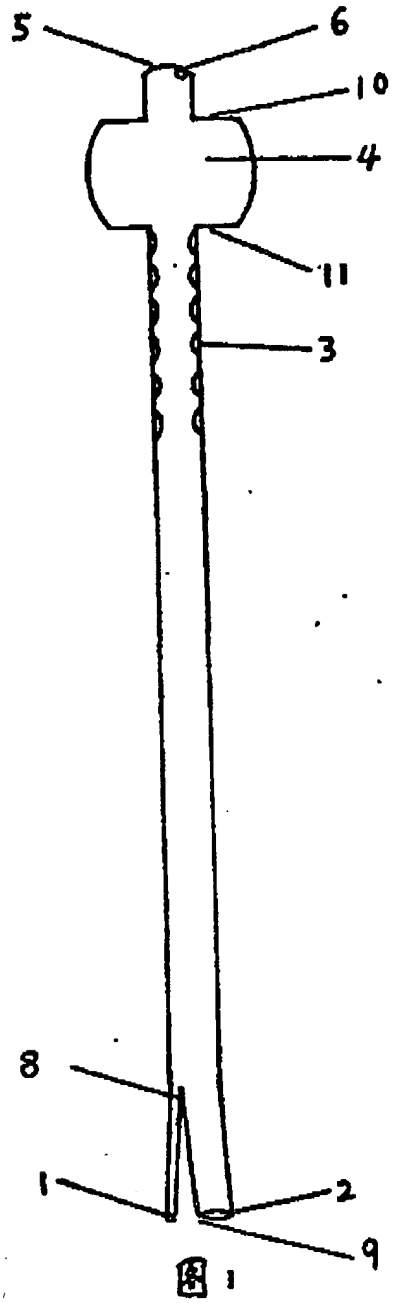

图 1

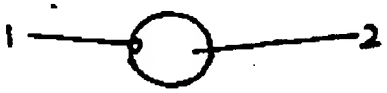

图 2

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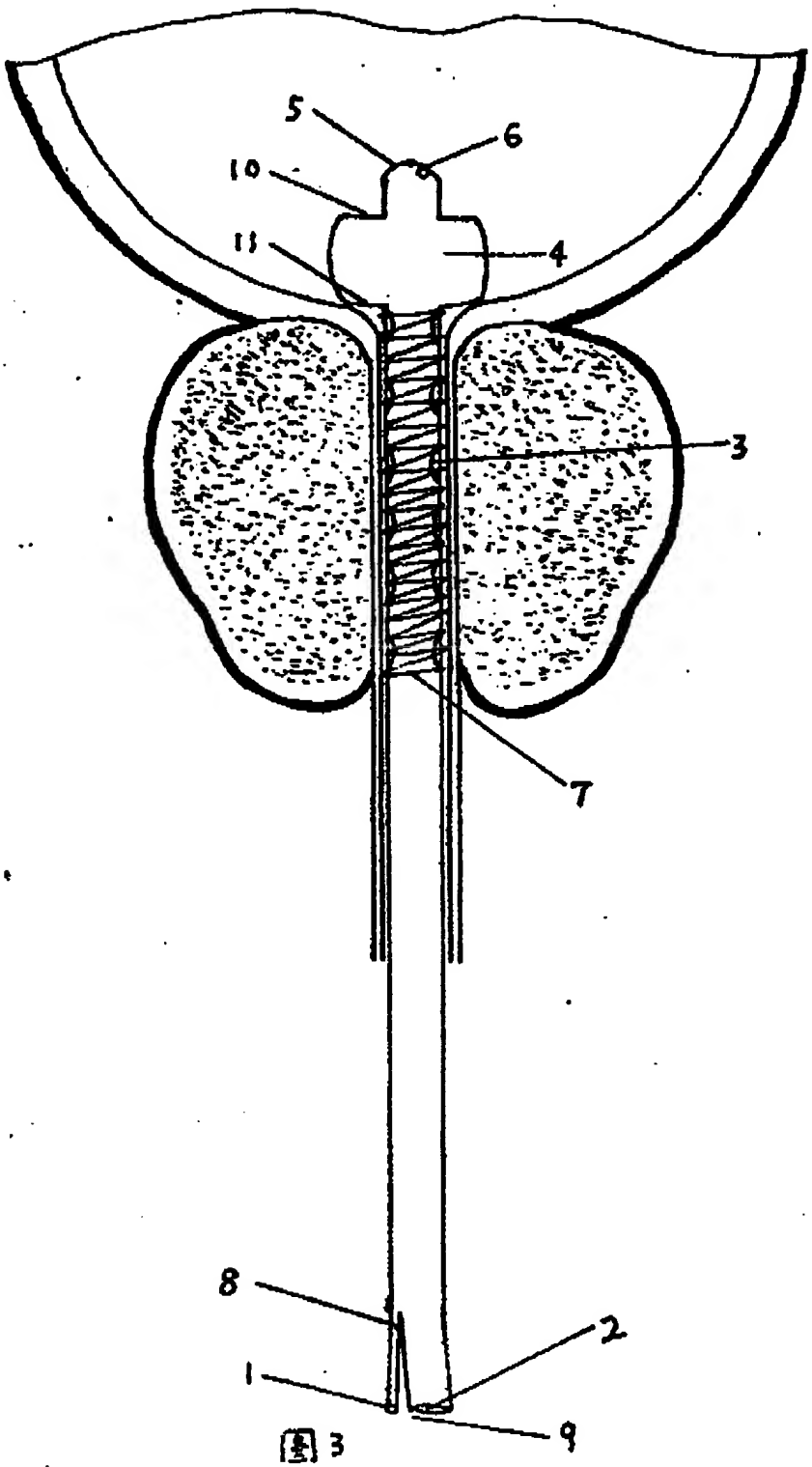

图 3

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[12] Specification of Application for Utility Model Patent

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Description 2 pages, Drawings 2 pages

[54] Title of invention: Memory alloy stent-positioning catheter for treatment of prostate hyperplasia

[57] Abstract

A memory alloy stent-positioning catheter for treatment of prostate hyperplasia, being a type of medical device. It consists of an inflatable/deflatable balloon added to an existing ordinary urethral catheter. This balloon is introduced into the bladder along with the positioning catheter. When inflated with air or liquid, the distal end of the balloon pushes tightly up against the bladder exit and thus effects accurate positioning. After the memory alloy stent, which is wound around the the catheter sidewall holes, recovers its former shape, [illegible] accurate positioning. In this way the objectives of dilating the prostate portion of the urethra and (or) the draining of urine are achieved.

(BJ) No. 1452

CLAIMS

1. A stent-positioning catether for the treatment of prostate hyperplasia, characterized by the fact that the proximal end of the catheter has a baloon and the distal end of the balloon, when inflated, pushes tightly up against the bladder exit.

2. The catheter as described in claim 1, characterized by the fact that it is made of plastic.

3. The catheter as described in claim 1, characterized by the fact that its distal end has two holes, one being a balloon injection port and the other being a urine drainage hole.

4. The catheter as described in claim 1, characterized by the fact that the catheter has uniformly distributed sidewall holes below the distal end of the balloon.

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DESCRIPTION

Positioning Catheter with Memory Alloy Stent for Treatment of Prostate Hyperplasia

The present utility model relates to a medical device. In particular, it relates to the implantation of a memory alloy stent for the treatment of prostate hyperplasia.

Hyperplasia of the prostate gland is a common disease among elderly men. Blockage of the bladder exit often results in urinary retention, difficulty in eliminating urine, and other such symptoms. A new method of treatment is to implant a memory alloy stent. However, current stent catheters are not able to achieve accurate positioning. The entire procedure must be carried out under X-ray observation and even then positioning is inaccurate in some patients, and it becomes necessary to repeatedly adjust the stent position.

The object of the present utility model is to provide a memory alloy stent-positioning catheter for the treatment of prostate hyperplasia. It can accurately implant a memory alloy stent without X-ray observation. This stent catheter can achieve accurate positioning.

The object of the present utility model is achieved as follows: The positioning catheter is made of plastic materials. Its total lengths are 25 cm, 27 cm, and 29 cm (not including length after the junction). The distal end of the catheter has two holes. One is a balloon injection port, and the other is a urine drainage hole. This hole connects with the catheter proximal opening and the sidewall holes where the memory alloy is wound. The sidewall holes are in two columns. They are uniformly arranged and come in three length specifications: 5 cm, 6 cm, and 7 cm. The balloon is 1–2 cm from the proximal end and consists of nondeformable plastic membrane. Its dimensions are 3 x 3 cm, and it can bear pressures above 2 kg/cm^2. It can achieve positioning after air is injected. When deflated, the plastic membrane adheres tightly to the catheter and does not add to the catheter's external diameter. The stent-positioning catheter can be easily removed through the stent lumen. The upper (proximal) end of the balloon catheter is oval and has an opening. It is connected with the urine drainage hole of the distal end.

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By adopting the above-described scheme, one can accurately implant the stent.

The following is a further description of the utility model in light of the drawings and embodiments below:

FIG. 1: Front view of the catheter

FIG. 2: Cross-sectional drawing of the catheter

FIG. 3: Drawing of an implanted catheter

In the figures: 1. balloon injection port, 2. catheter urine drainage hole, 3. catheter sidewall holes, 4. catheter balloon, 5. catheter proximal end, 6. proximal end opening, 7. stent, 8. junction, 9. catheter distal end, 10. balloon proximal end, 11. balloon distal end.

Use 1% dicaine 2 ml to anesthetize the mucosal lining of the urethra. Then use an urethral probe to dilate the urethra. At this point, taking advantage of the suppleness and deformability of titanium-nickel alloy at low temperatures, in saline water at approximately 0–10 °C, wind the stent 7 around the sidewall holes of the positioning catheter. After the urethra has been anesthetized, insert a sheathed tube into the urethra. Drainage of urine indicates that the bladder has been reached. Introduce the positining catheter with wound memory alloy stent through the sheath tube into the bladder. Remove the sheath tube. Inflate the balloon by injecting 15–30 ml of air or liquid through the balloon injection port. Inject 40–50 °C warm water through the urine drainage hole . The warm water passes through the catheter sidewall holes and comes into contact with the stent. The stent returns to its former shape and thus dilates the urethra or (and) drains urine. Release the air or liquid in the balloon. Remove the positioning catheter to complete the procedure.

DRAWINGS ATTACHED TO DESCRIPTION

[See original for drawings.]

FIG. 2

FIG. 1

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[See original for drawing.]

FIG. 3

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